



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee;

Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on May 21, 2013, from 8 a.m. to 5 p.m. and on May 22, 2013, from 8 a.m. to 4 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD 20879. The hotel phone number is 301-948-8900.

Contact Person: Jamie Waterhouse, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1611, Silver Spring, MD 20993-0002, Jamie.Waterhouse@fda.hhs.gov, 301-796-3063, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the Federal Register about last minute modifications that impact a previously announced advisory

committee meeting cannot always be published quickly enough to provide timely notice.

Therefore, you should always check the Agency's Web site at

<http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On May 21, 2013, the committee will discuss and make recommendations regarding the classification of one of the remaining preamendments class III devices, shortwave diathermy for all other uses except for the treatment of malignancies. The class III shortwave diathermy is a device that applies electromagnetic energy to the body in a radiofrequency band ranging between 13 megahertz to 27.12 megahertz and is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues.

On July 6, 2012 (77 FR 39953), FDA issued a proposed rule which, if made final, would make shortwave diathermy devices for all other uses class III requiring premarket approval (PMA) applications. In response to the proposed rule calling for PMAs, FDA received petitions under section 515(b)(2)(B) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(b)(2)(B)) requesting a change in classification. The reclassification petitions are available for public review and comment at www.regulations.gov under docket number FDA-2012-N-0378. The prior regulatory history of shortwave diathermy for all other uses has been discussed as part of the proposed rule (77 FR 39953).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA), or reclassify to class I or class II (subject to premarket notification (510(k))), as directed by section 515(i) of the FD&C Act.

On May 22, 2013, the committee will discuss and make recommendations regarding the 515(i) order issued by FDA on April 9, 2009 (Docket No. FDA-2009-M-0101), for one of the remaining preamendments class III devices, pedicle screw spinal systems, intended to treat degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1, or degenerative spondylolisthesis with objective evidence of neurologic impairment. Pedicle screw spinal systems are posterior spinal screw and rod systems intended as an adjunct to fusion for the treatment of degenerative disc disease, trauma, deformity, failed previous fusion, tumor, infection, and inflammatory disorders in the thoracolumbar spine.

On July 27, 1998 (63 FR 40025), FDA published a final rule classifying certain previously unclassified preamendments pedicle screw spinal systems and reclassifying certain postamendments pedicle screw spinal systems. On May 22, 2001 (66 FR 28051), FDA published a technical amendment to the final rule to include an intended use that was inadvertently omitted from the codified language in the rule. As described in the summary of revisions in the technical amendment, FDA changed the intended uses for which pedicle screw spinal systems are class III from “all other uses,” to “when intended to provide immobilization and stabilization of spinal segments in the thoracic, lumbar, and sacral spine as an adjunct to fusion in the treatment of degenerative disc disease and spondylolisthesis other than either severe spondylolisthesis (grades 3 and 4) at L5-S1 or degenerative spondylolisthesis with objective evidence of neurologic impairment.” Since the technical amendment, FDA has not established an effective date for the submission of PMAs for pedicle screw spinal systems with these class III indications for use; consequently, these systems have been subject to 510(k).

The discussion at the panel meeting will involve making recommendations regarding regulatory classification to either reconfirm to class III (subject to PMA), or reclassify to class I or class II (subject to 510(k)), as directed by section 515(i) of the FD&C Act.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 13, 2013. Oral presentations from the public will be scheduled between approximately 12 p.m. and 1 p.m. on May 21, 2013, and between approximately 10:45 a.m. and 11:45 a.m. on May 22, 2013. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 3, 2013. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 6, 2013.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact AnnMarie Williams (Annmarie.williams@fda.hhs.gov, 301-796-5966) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 4, 2013.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.